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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable added poisonous or deleterious substances in food by adopting tolerances through formal rulemaking pursuant to § 402(a)(2)(A) (21 U.S.C. § 342(a)(2)(A)), rather than by adopting informal action levels administered by case-by-case adjudication pursuant to § 402(a)(1) (21 U.S.C. § 342(a)(1)).

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

The National Peanut Council, Inc. ("NPC"), by its attorneys, files this brief as *amicus curiae* in support of the Petitioner, Frank Young, Commissioner of Food and Drugs, and respectfully urges the Court to reverse the judgment entered by the United States Court of Appeals for the District of Columbia Circuit in the above-captioned case. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

INTEREST OF *AMICUS CURIAE*

The National Peanut Council, Inc. ("NPC") is a non-profit Georgia corporation, chartered in 1940, which rep-

resents and serves individuals, companies, corporations, and associations engaged in, or providing goods or services to, the production, processing, marketing, or manufacturing of peanuts and peanut products. NPC members include peanut growers and affiliated associations, shellers, custom processors, brokers, manufacturers, and international and allied entities.

The subject matter of the instant case—whether the Food and Drug Administration ("FDA") is required to regulate unavoidable added poisonous or deleterious substances in food by means of tolerances promulgated through formal rulemaking, rather than by informal action levels resulting in case-by-case adjudication—is of great concern to NPC, since the specific substances at issue here, aflatoxins, are chemical byproducts of molds that grow on numerous agricultural commodities. Furthermore, NPC and its members would be adversely affected by an interpretation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 ("FDCA"), that renders adulterated all foods which contain detectable amounts of any unavoidable added poisonous or deleterious substance, unless and until a tolerance for each substance and food has been established and promulgated by the FDA.

The interest of NPC is predicated upon the substantial and far-reaching consequences of the result of the instant case. The concern of the *amicus curiae* is that the Court, in formulating the principles to govern the interpretation of key sections of the FDCA involved in the present case, should have the benefit of NPC's views, which may not otherwise be presented in the arguments of the parties, in order to be aware of the broad ramifications of its decision herein.

STATEMENT OF THE CASE

This case presents a challenge to the FDA's method of regulating the interstate commerce of foods which evidence any added poisonous or deleterious substance that is required in the production of food or that cannot be avoided by good manufacturing practices. Since the enactment of the FDCA in 1938, FDA has regulated substances like aflatoxins principally by issuing action levels, which announce the level of the particular substance that FDA regards as resulting in adulteration under § 402(a)(1).[1]

Respondents brought this suit to challenge FDA's implementation of the adulteration provisions of the FDCA to aflatoxins in corn products. Respondents contended that: (1) FDA should be compelled to adopt a formal aflatoxin tolerance pursuant to § 406,[2] as opposed to an informally implemented action level; (2) the action level, in the alternative, should be made subject to notice-and-comment rulemaking; and (3) certain exemptions to the action level were contrary to law. The United States District Court for the District of Columbia noted that the FDA had promulgated a final rule governing the use of action levels and formal tolerances,[3] that the language of § 406 had been interpreted by FDA "to mean that, in its discretion, it may decide that a tolerance is not necessary to protect the public health and therefore can decline to establish one,"[4] and that an agency's interpretation of its statute is entitled to substantial deference. Therefore, the court found that FDA's construction of § 406 was reasonable and that § 406 "confers discretionary, not mandatory, authority on the agency to

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[1] 21 U.S.C. § 342(a)(1).

[2] 21 U.S.C. § 346.

[3] 42 Fed. Reg. 52814 (September 30, 1977), codified in 21 C.F.R. § 109.6 (food for human consumption) and § 509.6 (animal feed).

[4] Pet. App. 31a.

establish tolerances." Pet. App. 31a-32a (footnote omitted). The court granted FDA's motion for summary judgment on all three issues, concluded that "action levels" were general statements of policy not requiring notice-and-comment rulemaking, and further stated that the exemptions granted were within the agency's discretion. Pet. App. 32a-34a.

The United States Court of Appeals for the District of Columbia Circuit reversed and held that "the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated."[5] The sole justification for the court's holding was its interpretation of the language of § 406 that "the Secretary shall promulgate regulations limiting the quantity [of unavoidable or required added poisonous or deleterious substances in food] to such extent as he finds necessary for the protection of public health."[6] The court interpreted the clause "to such extent as he finds necessary for the protection of public health" as not modifying "the pivotal word 'shall',"[7] and inferred that the "Secretary must promulgate regulations embodying tolerances."[8] The court reiterated its holding by stating that, "(s)ince the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 7a.

In interpreting the FDCA to require tolerances, the court rejected FDA's longstanding interpretation of the FDCA,[9] characterized the legislative history supporting

[5] Pet. App. 15a.

[6] 21 U.S.C. § 346.

[7] Pet. App. 7a.

[8] Pet. App. 7a.

[9] Pet. App. 6a.

FDA's interpretation as inconclusive,[10] dismissed all relevant cases on the ground that they did not address the issue *sub judice*,[11] and cited no judicial, legislative, or administrative authority that has ever interpreted the FDCA in the manner adopted by the court.

SUMMARY OF ARGUMENT

In support of Petitioner, NPC respectfully urges that the Court reverse the judgment entered by the United States Court of Appeals for the District of Columbia Circuit for the following reasons:

(1) The District of Columbia Circuit's interpretation is not supported by the language or plain meaning of the FDCA,

(2) The District of Columbia Circuit's interpretation is not supported by the legislative history of the FDCA,

(3) The District of Columbia Circuit's interpretation is in conflict with FDA's longstanding administrative interpretation, which was acknowledged and unaltered by Congress and is entitled to substantial deference,

(4) The District of Columbia Circuit's interpretation violates a sound principle of statutory construction, that a statute be construed so as to give effect to all of its provisions, and has the effect of rendering the key adulteration standard of § 402(a)(1) totally inoperative, and

(5) The District of Columbia Circuit's interpretation is not supported by prior case law.

Therefore, NPC respectfully suggests that Congress has conferred upon FDA the customary agency discretion to determine whether, *i.e.*, to what extent the protection of public health requires, a formal tolerance be promulgated in any given circumstance.

[10] Pet. App. 9a-11a.

[11] Pet. App. 13a, 15a.

ARGUMENT

I. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA IS NOT SUPPORTED BY THE LANGUAGE OR PLAIN MEANING OF THE FDCA

The FDCA, at §§ 402(a) and 406, delegated authority to the FDA to regulate added poisonous or deleterious substances in food. It is not disputed that aflatoxin is an unavoidable added poisonous or deleterious substance; however, the FDCA does not define any aflatoxin-tainted corn to be adulterated absent (1) FDA's determination that the presence of aflatoxin in corn may render the food injurious to health, or (2) FDA's discretionary promulgation of a formal tolerance. The analysis presented below clearly demonstrates that the interpretation of the District of Columbia Circuit is not supported by the language or plain meaning of §§ 402(a) and 406.

The pertinent part of § 402(a) provides that:

> A food shall be deemed to be adulterated—
>
> (a) *Poisonous, insanitary, or deleterious ingredients.* (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406 [21 U.S.C. § 346], or (B) if it is a raw agricultural commodity and it bears or contain a pesticide chemical which is unsafe within the meaning of section 408(a) [21 U.S.C. § 346a(a)], or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409 [21 U.S.C. § 348].

Under the first clause of § 402(a)(1), any food containing any added poisonous or deleterious substance is deemed adulterated, only if the added poisonous or deleterious substance may render the food injurious to health. This Court held, in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 410 (1914), that, under the plain meaning of subdivision five of § 7 of the Food and Drugs Act of 1906,[12] the mere presence of an added poisonous or deleterious substance does not render a food adulterated.[13] The added substance must be shown to be present in such amounts that might render the food injurious to health.

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[12] Section 7 of the Food and Drugs Act of 1906, 34 Stat. 769, provides in pertinent part:

> Sec. 7 That for the purposes of this act an article shall be deemed to be adulterated: . . . In the case of food:
>
> . . .
>
> Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health.

[13] (W)e find that the fifth subdivision of § 7 provides that food shall be deemed to be adulterated: "If it contain(s) any added poisonous or other added deleterious ingredient *which may render such article injurious to health.*" The instruction of the trial court permitted this statute to be read without the final and qualifying words, concerning the effect of the article upon health. If Congress had so intended the provision would have stopped with the condemnation of food which contained any added poisonous or other added deleterious ingredient. In other words, the first and familiar consideration is that, if Congress had intended to enact the statute in that form, it would have done so by choice of apt words to express that intent. It did not do so, but only condemned food containing an added poisonous or other added deleterious ingredient when such addition might render the article of food injurious to health.

United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 410-411 (1914) (emphasis in original).

In *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), the Court, construing the Federal Food, Drug, and Cosmetic Act of 1938, held that the rule of *Lexington Mill* continued to apply under the first clause of § 402 (a) (1).[14]

Since the FDA has not determined that the mere presence of any amount of aflatoxin in food may render such food injurious to health, foods containing aflatoxin are not deemed to be adulterated under the first clause of § 402(a)(1). We turn to the adulteration standard set forth in § 406, which is referred to by § 402(a)(2)(A), under which a food is deemed adulterated if it contains "any added poisonous or deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406." [15]

The initial part of § 406 provides that:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)]; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)].

[14] *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 160-1 (1958); *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1155-6 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157, 159 (5th Cir. 1980). *See also, Certified Color Industry Committee v. Secretary of Health, Education & Welfare*, 236 F.2d 366, 869 (2d Cir. 1956); H.R. Rep. No. 2356, 82d Cong., 2d Sess. 21-22 (June 30, 1952).

[15] Other more specific statutory standards are prescribed in §§ 402(a)(2)(B) and 408 for registered pesticides in foods; in §§ 402(a)(2)(C) and 409 for food additives in foods; in §§ 402(c) and 706 for color additives; and in §§ 402(a)(2)(D) and 512 for new animal drugs. 21 U.S.C. §§ 342, 346a, 348, 376, and 360b.

Thus, an added poisonous or deleterious substance shall be deemed to be "unsafe" for purposes of § 402(a)(2)(A) in two circumstances: (1) under the first clause of § 406, any amount of such substance is unsafe if it is not required in production or is not unavoidable; and (2) under the third clause of § 406, if a tolerance has been adopted for an added poisonous or deleterious substance that is required in production or is unavoidable, the substance is deemed unsafe if it exceeds the quantity prescribed by a tolerance. The remainder of § 406 provides that:

> While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a) [21 U.S.C. § 342(a)(1)]. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

The language of § 406 prescribes no safety standard for added poisonous or deleterious substances which are required or unavoidable and for which a tolerance has not been promulgated. Neither criteria of § 406 for added poisonous or deleterious substances to be deemed "unsafe" applies to an added poisonous or deleterious substance which is required in production or is unavoidable and for which no tolerance has been prescribed. This

is not an omission by Congress in drafting the FDCA. The adulteration standard set forth in § 402(a)(1) remains applicable for added poisonous or deleterious substances and FDA promulgates and enforces action levels limiting the presence of such substances under that section.

The language and plain meaning of § 406 does not *require* FDA to establish formal tolerances. The second clause of § 406—"but when such [added poisonous or deleterious] substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such as he finds necessary for the protection of public health,"—is not a directive that compels FDA to promulgate formal tolerances. The Court of Appeals held that the phrase "to such extent as he finds necessary for the protection of the public health" does not modify the pivotal word "shall," and that the overall structure of the statutory scheme supports its conclusion that the phrase explains the standard that the Secretary is to employ in setting formal tolerance. Pet. App. 7a. The Court of Appeals' interpretation is in error in both instances.

The plain meaning of the language of § 406 is to confer authority (*i.e.*, permission) upon the Secretary to promulgate tolerances. The critical phrase noted above modifies the pivotal word "shall" and expresses the Congressional intent that tolerances may be utilized, in the Secretary's discretion, to effect the purpose of the FDCA—to protect public health.[16] The last sentence of § 406 explains the quantitative standard the Secretary is required to employ in setting the tolerance, the critical phrase performs no such office.

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[16] *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Two Bags, Poppy Seeds*, 147 F.2d 123 (6th Cir. 1945); *Barnes v. United States*, 142 F.2d 648 (9th Cir. 1944).

The analysis offered by the Court in *Lexington Mill*,[17] supports Petitioner's interpretation and plain meaning analysis. If Congress had so intended that § 406 require FDA to establish tolerances, the language of the second clause of § 406 would have ended with the language—"the Secretary shall promulgate regulations limiting the quantity therein or thereon." Congress did not do so, but only directed the Secretary to establish tolerances "to such extent as he finds necessary for the protection of public health." Furthermore, it must be noted that Congress, in including the last phrase of the second clause of § 406, added a phrase that expressed the general purpose of the entire FDCA.[18] This express redundancy is entitled to even greater deference to its modifying position and interpretation.

II. THE COURT OF APPEALS' INTERPRETATION IS NOT SUPPORTED BY THE LEGISLATIVE HISTORY OF THE FDCA

The legislative history of the FDCA does not support the Court of Appeals' interpretation that FDA is required to promulgate tolerance levels for required or unavoidable added poisonous or deleterious substances. The report accompanying S. 5, a bill to amend the FDCA, as reported to the Senate,[19] described section 304(a), enacted as § 406(a), to "authorize the establishment of tolerances for the protection public health in those instances where the addition of the poison is required or cannot be avoided," [20] and "delegate authority for the

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[17] *See* n.13.

[18] *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (D. Md. 1944).

[19] S. Rep. No. 686, 74th Cong., 1st Sess. (May 13, 1935).

[20] *Id.* at 3.

establishment of tolerances so limiting the amount of poisons as to protect the public health." [21]

On August 21, 1937, a subcommittee of the Committee on Interstate and Foreign Commerce of the House of Representatives published the text of the food, drug, and cosmetic bill, known as Committee Print No. 3, which was a revised substitute for S. 5 and incorporated H.R. 300, introduced by Mr. Chapman of Kentucky. The subcommittee offered no reason for the insertion of the word "shall" in § 406(a).[22]

Section 406(a) was construed and compared to the law in existence in 1938 as follows:

> Section 406, in subsection (a), provides for a fairer and more effective control of the addition of poisons to food than does the present law. This subsection first prohibits the unnecessary addition of poisons. *Where such additions are necessary, the establishment of tolerances is authorized, based upon the practical necessities for the use of poisonous substances.* It is well recognized that an adequate fruit and vegetable supply could not be brought to maturity without the use of toxic insecticides and fungicides. But the situation is made extremely complex by the number of poisonous substances used for different crops in different localities, and by contaminations which unavoidably occur in many manufacturing processes. The purpose of the subsection is to insure that the total amount of poisons the consumer receives will not be sufficient to jeopardize health. The needs of each branch of the food-producing industry can be met and the public health can be adequately protected.

[21] *Id.* at 5. S. 5, introduced by Senator Copeland of New York, passed the Senate on March 3, 1937.

[22] *See House Committee on Interstate and Foreign Commerce*, 75th Cong., 1st Sess., Committee Print No. 3 (August 19, 1937), *reprinted in* 81 Cong. Rec. (Appendix) 2341, 2344 (August 21, 1937).

H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (April 14, 1938) (emphasis added).

Prior to the 1954 pesticide amendments to the FDCA, the Select Committee to Investigate the Use of Chemicals in Food Products issued a report, entitled "Food." [23] After referring to § 402(a)(2) and citing § 406 in full, the report stated:

> *The primary purpose of section 406 was to provide a means by which maximum residue tolerances on food could be established for needed pesticides so as to protect the public health.* The Food and Drug Administration has completed hearings to establish tolerances on a large number of pesticides, and regulations are now being formulated. But the setting of tolerances does not give the Food and Drug Administration any advance control over the use of pesticides. Unless the manufacturer conducts adequate chronic toxicity tests for a new pesticide, the Government is powerless to afford the consumer any protection until it completes its own toxicity tests and conducts a formal public hearing for the purpose of issuing tolerance regulations. Both procedures consume more time than is consistent with efficient protection of the public health.

H.R. Rep. No. 2356, 82d Cong., 2d Sess. 22 (June 30, 1952) (emphasis added).

On July 14, 1953, the Subcommittee No. 2 of the Interstate and Foreign Commerce Committee held hearings on H.R 4277 of the 83d Congress, 1st Session, a pesticide amendment to the FDCA. The purpose of H.R. 4277 was to protect citizens from harmful chemical additives in pesticides by amending § 402(a)(2) to exclude pesticides from the language of § 406 and subject pesticides, under a final clause in § 402(a)(2), to a proposed new section, § 407 (subsequently enacted as § 408, 21 U.S.C. § 346a). As Congress desired that chemical additives in pesticides

[23] H.R. Rep. No. 2356, 82d Cong., 2d Sess. (June 30, 1952).

not be utilized without a tolerance having been promulgated, § 407 provided, in pertinent part, that:

> Any poisonous or deleterious pesticide added to food shall be deemed unsafe . . . [under § 402(a)(2)] unless (1) the quantity thereof does not exceed the limits of a tolerance prescribed by the Administrator under paragraph (b) of this section; or (2) the pesticide has been exempted from the requirement of a tolerance by the Administrator under paragraph (c) of this section.

§ 407(a), H.R. 4277, 83d Cong., 1st Sess.

Congress proposed and subsequently adopted a modified version of this language [24] to compel the Administrator to issue a pesticide tolerance or exempt a pesticide from the tolerance requirement, since Congress knew that the Department of Agriculture had held three years of hearings and expended some $500,000 in experiments and had not issued any tolerances for pesticides in foods under proceedings authorized by §§ 406 and 701(e) of the FDCA.[25]

In hearings before the Committee on Interstate and Foreign Commerce on H.R. 7125, 83d Cong., 2d Sess. (March 8, 1954),[26] Mr. Hinsaw introduced Mr. H. Thomas Austern, General Counsel of the National Canners Association, and placed Mr. Austern's letter, dated February 8, 1954, in the record. Speaking to the effect of H.R. 7125, a bill to amend the FDCA with respect to

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[24] *See* § 408(a), 21 U.S.C. § 346a(a).

[25] *See Hearings Before the Subcommittee No. 2 of the Interstate and Foreign Commerce Committee*, 83d Cong., 1st Sess. 118-121 (July 14, 1953) (Testimony of Mr. Crawford concerning H.R. 4277).

[26] H.R. 7125, similar in purpose and design to H.R. 4277 introduced on March 26, 1953, was introduced following conferences between authors of H.R. 4277, government officials, and farm and industry groups. *See* H.R. Rep. 1385, 83d Cong., 2d Sess. 4-5 (March 23, 1954).

residues of pesticide chemicals in or on raw agricultural commodities, Mr. Austern's letter stated:

> The association endorses this bill as introduced on January 11. This proposed legislation will, if passed, amend the Federal Food, Drug, and Cosmetic Act by providing a new procedure for the establishment of tolerances for residues of pesticide chemicals in or on raw agricultural commodities only. It is the understanding of the National Canners Association that after passage of this bill processed food will be in exactly the same position as before in that tolerances for pesticide residues with respect to processed food *may* be established under section 406 of the act; that *in the event* the Secretary acts to establish a tolerance for residues on processed foods under section 406 actions for adulteration will be taken under section 402(a)(2), but if the Secretary has not acted under section 406 any action for adulteration because of excessive pesticide residue in the processed food will still be taken under section 402(a)(1). This understanding of the canning industry is, we are advised, shared by Dr. Miller, by the FDA, and by all others interested in the legislation. The endorsement by the National Canners Association of H.R. 7125 on behalf of the canning industry is predicated on this understanding and the hope that your committee report will make it explicitly clear that the adulteration of processed foods will be dealt with exactly as before this amendment of the act.

Hearings Before the Committee on Interstate and Foreign Commerce on H.R. 7125, 83d Cong., 2d Sess. 31 (March 8, 1954).

The report concerning H.R. 7125 [27] demonstrates that Congress recognized the Secretary's discretion to promulgate tolerances and problems of issuing tolerances under § 406:

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[27] H.R. Rep. No. 1385, 83d Cong., 2d Sess. (March 23, 1954).

Existing law.

Under existing law, added poisonous and deleterious substances—and most pesticide chemicals fall in this class—must be kept out of foods unless they are required in production or cannot be avoided by good manufacturing practice. When such a substance is required in production—as many pesticide chemicals are required in growing agricultural crops—a tolerance *may* be established by the Secretary of Health, Education, and Welfare, but only after a formal public hearing. (The maximum amount of residue that may lawfully remain in or on the food is commonly referred to as a tolerance.) Detailed findings of fact and conclusions must be made by the Secretary as to the required use of the pesticide and the residue levels that may safely be tolerated.

Need for more legislation.

Regulations limiting the amount of pesticidal residue which may remain in or on food have been issued under the present law in only one instance, although the law authorizing such regulations has been in effect for over 15 years. During all that time control has been exercised through *unofficial and informal tolerances* [*i.e.*, action levels]. In 1950, lengthy public hearings were held for the purpose of establishing official tolerances (the maximum amount of poisonous of deleterious residue which may legally remain in or on food) for fresh fruits and vegetables. These hearings, at a cost of nearly a half-million dollars to Government, to industry, to agricultural organizations, and to the various land-grant colleges, produced a very large volume of evidence that had not theretofore been gathered together, but the record is still under consideration by the Government and the necessary tolerances have not yet been issued. This has been responsible for uncertainty under the law. It has handicapped the Government in enforcing the law, the grower in complying with the law, and the pesticide manufacturer and Federal and State agencies in discharging their responsibility for advising

and making recommendations to the grower with respect to the use of pesticide chemicals. This, together with the introduction of a large number of new pesticide chemicals, some of which are known to be toxic, has been responsible for concern that existing law is inadequate to protect the public health.

It has been generally recognized that a primary reason why tolerances have not been established to control agricultural usage of pesticide chemicals as intended by Congress has been the cumbersome, time-consuming, and impracticable procedure prescribed by existing law.

H.R. Rep. No. 1385, 83d Cong., 2d Sess. 2-3 (March 23, 1954) (emphasis added). Therefore, pertinent language of H.R. 7125 directed the Secretary of Health, Education, and Welfare to issue tolerances or exemptions from the tolerance requirements of § 408 within one hundred and eighty (180) days of the date a petition is filed under § 408(d) and specifically provided that a residue of a poisonous or deleterious pesticide chemical will be deemed unsafe under § 402(a)(2) if no tolerance or exemption has been established for it.[28]

Thus, Congress explicitly mandated tolerances or exceptions from tolerance for poisonous or deleterious pesticide chemical residues and, with knowledge that tolerances were not being established by the Secretary, repeatedly failed to amend § 406 to establish a similar mandate for unavoidable added poisonous or deleterious substances. The extended legislative history of the FDCA does not support the Court of Appeals' interpretation that § 406 requires the promulgation of tolerances or that unavoidable added poisonous or deleterious substances will be deemed adulterated in the absence of tolerances.

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[28] § 408(a), H.R. Rep. No. 2385, 83d Cong., 2d Sess. 7-8 (March 29, 1954); S. Rep. 1635, 83d Cong., 2d Sess. 4-7 (June 25, 1954).

III. FDA'S LONGSTANDING ADMINISTRATIVE INTERPRETATION OF THE FDCA, WHICH WAS RECOGNIZED AND UNALTERED BY CONGRESS IN 1954, IS IN CONFLICT WITH THE COURT OF APPEALS' INTERPRETATION

As cited above, Congress noted FDA's interpretation of §§ 402 and 406 in its 1954 legislative history and repeatedly chose not to amend §§ 402 and 406 to alter FDA's interpretation. Thus, FDA rightfully continues to adhere to its interpretation of §§ 402 and 406, as demonstrated in its 1974 proposal relating to the adoption of action levels[29] and its preamble to the promulgation of final regulations,[30] incorporated as Part 109—Unavoidable Contaminants in Food for Human Consumption and Food —Packaging Material, Chapter I of Title 21, of the Code of Federal Regulations, which stated:

> In establishing an action level, the Commissioner must consider the extent to which the contaminant is unavoidable, which is the policy embodied in section 406 of the act.
>
> . . .
>
> In setting a tolerance or action level the Commissioner considers the other ways in which the consumer may be affected by the same substance or other substances.

39 Fed. Reg. 42738 (December 6, 1974). FDA has repeatedly expressed its interpretaiton of §§ 402 and 406 as *permitting* the establishment of tolerances:

> "Section 406 of the act *permits* the establishment of tolerances for added poisonous or deleterious substances in food . . ."

39 Fed. Reg. 42743 (December 6, 1974),

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[29] 39 Fed. Reg. 42743 (December 6, 1974).

[30] 42 Fed. Reg. 52814 (September 30, 1974).

> Section 406 was included in the 1938 act to *permit* the establishment of tolerances for added poisonous or deleterious substances which are required in the production of food or otherwise cannot be avoided by good manufacturing practice. A limitation may be placed upon such substances to the extent necessary for the protection of the public health. Although formal tolerances under section 406 have not been used by the Food and Drug Administration, except for the tolerance for PCB's published in the *Federal Register* of July 6, 1973 (38 FR 18096), informal action levels have frequently been utilized to implement this provision of the law and a number of those action levels exist today.

39 Fed. Reg. 42744 (December 6, 1974), and

> When a tolerance is established under the provisions of section 406, the act requires it to be set at the level necessary for the protection of the public health taking into account the extent to which the substance cannot be avoided and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.
>
> At times it will not be appropriate to establish a formal tolerance. *The Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance*, as is indicated by the language of section 406 of the act recognizing that an adulteration charge can be made under section 402(a)(1) of the act when no tolerance is in effect. Section 306 of the act has long been interpreted to permit the Food and Drug Administration to establish action levels in implementing the adulteration provisions of the act.

39 Fed. Reg. 42745 (December 6, 1974) (citations omitted, emphasis added).

Thus, for almost fifty years, FDA has adopted the interpretation that § 406 grants discretionary authority to establish tolerances, and during that time has promul-

gated few tolerance levels, but an enormous number of action levels. In the hearings addressing the 1954 amendments to the FDCA, Congress recognized FDA's interpretation of §§ 402 and 406 and allowed the language of those sections to remain unaltered with respect to required or unavoidable added poisonous or deleterious substances. A comparison of the language and structure of § 408(a)-(c)[31] of the 1954 amendments with § 406 clearly reveals that the intent of Congress was to mandate that tolerance levels or exemptions from a tolerance requirement be established for pesticide residues in foods.[32] The language and structure of the pesticide chemical amendments are a model of clarity and purpose. Section 402(a)(2) was amended to deem foods containing pesticide chemicals "adulterated," if such food contain added pesticide chemicals which are "unsafe" under § 408(a).[33] Section 408(a) then defined any added poisonous or deleterious pesticide chemical to be "unsafe" for purposes of § 402(a)(2)(B) *unless* (1) a tolerance had been established and the quantity of such pesticide chemical is below the tolerance level prescribed,[34] or (2) the pesticide chemical had been exempted from the tolerance requirement.[35]

Significantly, Congress failed to alter the language or structure of § 406 to parallel that of § 408 and, by its inaction, implicitly authorized and sanctioned the interpretation of § 406 that permits, but does not require, FDA to establish tolerance levels for unavoidable added poisonous or deleterious substances which are not pesticide chemicals.

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[31] 21 U.S.C. § 346a(a)-(c).

[32] § 408(a); 21 U.S.C. § 346a(a).

[33] § 402(a)(2)(B); 21 U.S.C. § 342(a)(2)(B).

[34] § 408(a)(1), 21 U.S.C. § 346a(a)(1).

[35] § 408(a)(2), 21 U.S.C. § 346a(a)(2).

IV. THE COURT OF APPEALS' INTERPRETATION VIOLATES THE PRINCIPLE OF STATUTORY CONSTRUCTION THAT A STATUTE WILL BE CONSTRUED SO AS TO GIVE EFFECT TO ALL OF ITS PROVISIONS

As a general principle of statutory construction, a statute will be construed so as to give effect to all of its provisions. *See, e.g., Dickerson v. New Banner Institute, Inc.*, 460 U.S. 103, 118 (1983). However, the District of Columbia Circuit's unprecedented interpretation of §§ 402 and 406 renders meaningless and superfluous the key adulteration provision of § 402(a)(1) that foods containing added substances be deemed adulterated if the substance may render the food injurious to health. Sections 402(a) and 406 regulate added poisonous or deleterious substances under three classifications: (1) substances which are not required or unavoidable, (2) substances which are required or unavoidable and for which a tolerance has been established, and (3) substances which are required or unavoidable and for which a tolerance has not been established. Substances within the first classification are absolutely banned by §§ 402(a)(2)(A) and 406, and thus the "may render" standard of § 402(a)(1) has no application to such substances. Likewise, § 402(a)(1) has no application to substances within the second classification, since §§ 402(a)(2)(A) and 406 explicitly displace § 402(a)(1) when a tolerance has been promulgated for required or unavoidable added poisonous or deleterious substances. Thus, § 402(a)(1) can only apply to the third classification—required or unavoidable added poisonous or deleterious substances for which no tolerance has been established. The Court of Appeals interprets § 406 as if it provides that any required or unavoidable added poisonous or deleterious substance is deemed unsafe, unless a tolerance has been established. If this were the case, then §§ 402(a)(2)(A) and 406 would govern the third classification of substances, and § 402(a)(1) would be rendered totally inoperative. This is contrary

to the intent of Congress and the sound principle of statutory construction noted above. The Court should strive to interpret these provisions consistently since §§ 402 (a)(1) and 402(a)(2)(A) were enacted together in 1938.

Thus, if unavoidable added poisonous or deleterious substances must be regulated by tolerances under § 406, no purpose or effect remains for the first clause of § 402(a)(1). The Court of Appeals' interpretation renders § 402(a)(1) inoperative and meaningless, clearly disregards the intent of Congress, violates a sound principle of statutory construction, and must be reversed.

V. CASE LAW DOES NOT SUPPORT THE COURT OF APPEALS' INTERPRETATION

Ample case law on the very issue before this Court supports Petitioner's position. In *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980), Chief Judge Arnow noted that "Anderson also contended that FDA was required to establish a tolerance for mercury in swordfish under 21 U.S.C. § 346 (1975) [§ 406]. The court ruled prior to trial that this contention was without merit." 447 F. Supp. 1151, 1153, n.2. The court does not claim, as the District of Columbia Circuit implied, that defendant's contention was that FDA was required to establish tolerances under § 406 *before* taking enforcement action pursuant to the FDCA. In fact, the issue of whether FDA is required to establish tolerances arose from Anderson's complaint for declaratory and injunctive relief, not from the enforcement action asserted by the United States.[36]

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[36] The "two cases were consolidated and tried jointly because they shared fundamental questions of fact and law." 447 F. Supp. 1151, 1153.

In *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), an action to enjoin shipment of aflatoxin-tainted corn, the Fifth Circuit stated:

> The 20 ppb level proposed by the Government is the Food and Drug Administration's "action level" for aflatoxin in corn. An action level, to be defined properly, must be explained in the broader context of the FDA's general regulatory scheme. *In implementing the Act, the FDA either may adopt formal regulations, 21 U.S.C. § 346, or may litigate alleged violations on a case-by-case basis.* Although the Act makes illegal any amount of substance which "may render (food) injurious to health" 21 U.S.C. § 342(a)(1) the FDA is not required to seek to enjoin, prosecute or otherwise litigate "minor violations" of the Act. 21 U.S.C. § 336. To guide its prosecutorial discretion in the bringing of non-rule enforcements of the Act the FDA may establish certain inhouse guidelines called action levels. Since 1969 the action level for aflatoxin in corn has been 20 ppb. This means that since 1969 the FDA's internal policy has been to try to prevent the shipment of corn containing more than 20 ppb of aflatoxin, but not of corn containing 20 ppb or less.

Id. at 151 (emphasis added). The court held that, on the evidence presented, it was clearly erroneous to find that amounts of aflatoxin between 20 ppb and 100 ppb do not adulterate corn and enjoined shipment of corn containing more than 20 ppb of aflatoxin. Thus, the Court expressly sanctioned FDA's regulation of aflatoxin in corn by issuing action levels rather than tolerances. The Court of Appeals' characterization of *Anderson Seafoods* and *Boston Farm Center*, as involving only the ability of the United States to prohibit shipment of food without having first established a tolerance, is an inappropriate and unduly narrow view of the issues arising in these cases. The critical issue is the manner in which FDA must regulate food under the FDCA,

whether or not it permits shipment of such food. The Court of Appeals' attempt to distinguish the above cases, on the basis that they simply do not speak to the agency's refusal to establish a tolerance while permitting shipment, is absurd. The *Boston Farm Center* court expressly noted that "(t)o an extent the statutory scheme permits the FDA to adopt a relatively *ad hoc* case-by-case approach to regulating the poisons in our food," *id.* at 152-3, and it is common sense that, should FDA decide not to bring an enforcement action, FDA is permitting shipment.

While courts have expressed their belief in dicta that § 406 "apparently mandated that the FDA establish tolerances for added poisonous or deleterious substances which are required or unavoidable in the production of food," *United States v. General Foods Corp.*, 466 F. Supp. 740, 785 (N.D.N.Y. 1978), *aff'd*, 591 F.2d 1332 (2d Cir. 1978), such statements do not support the Court of Appeals' unprecedented interpretation, which reverses an FDA practice of almost fifty years' duration. Furthermore, the Court of Appeals cannot place reliance upon *United States v. Goodman*, 353 F. Supp. 250 (E.D. Wisc. 1972), *aff'd*, 486 F.2d 847 (7th Cir. 1973), *aff'd sub nom., United States v. Ewig Bros. Co., Inc.*, 420 U.S. 945 (1975), as the intent of Congress in the 1954 pesticide amendments to the FDCA, which culminated in the § 408 requirement that the FDA establish tolerances or grant exemptions from the tolerance requirement for pesticides, is not analogous to § 406's grant of authority to promulgate tolerances.

In *Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F.2d 866 (2d Cir. 1956), the court stated that "(s)ection 406(a), 21 U.S.C. § 346(a), gives the Secretary *permission* to set up tolerances for added poisonous or deleterious substances which are required or cannot be avoided by good manufacturing practice," *id.* at 868, and held that the Secretary

could not be required to establish such tolerances for coal-tar colors.

The foregoing analysis of case law clearly demonstrates the Court of Appeals' error of summarily dismissing all precedent before it and provides sound justification for Petitioner's request that this Court reverse the Court of Appeals' unprecedented interpretation of the FDCA, which renders a substantial portion of our food supply adulterated and bars interstate shipment of such commodities.

CONCLUSION

For the reasons set forth herein, the National Peanut Council, Inc., as *amicus curiae* in support of Petitioner, respectfully urges this Court to reverse the Judgment and opinion of the United States Court of Appeals for the District of Columbia Circuit.

Respectfully submitted,

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